UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: November 20, 2018

Subject: Efficacy Review for JigSAW,
EPA File. No. 84150-1,
DP Barcode: #448190
E-submission: #30553

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 11/19/2018

To: Jacqueline Hardy RM34/Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: GOJO Industries, Inc.
P.O. Box 991
Akron, OH 44309

Formulation from the Label:

Active Ingredient	% by wt.
Ethyl alcohol	20.0%
Other Ingredients	80.0%
Total	100.0%

I. BACKGROUND

Product Description (as packaged and applied): To be applied as towelette wipes.

Submission Type: Label Amendment

Requested Action: Registrant is requesting to amend the product label to add additional organism claims and to update the Emerging Pathogens Statement to include small, non-enveloped viruses.

Documents Submitted for Consideration:

- A letter to EPA (dated June 27, 2018)
- Application for Pesticide Registration (EPA form 8570-1)
- Certification with Respect to Citation of Data (EPA form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Request to Make Claims Against Emerging Viral Pathogens (a letter)
- 23 efficacy studies (MRID Nos. 50615701 - 50615723); Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included with the study.
- Proposed product label dated June 27, 2018.

II. USE DIRECTIONS

SANITIZATION DIRECTIONS

[TO] [CLEAN] [and] [SANITIZE] HARD, NONPOROUS NON-FOOD CONTACT SURFACES:
Visible soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wipe surface [to be sanitized] until completely wet. Treated surfaces must remain wet for 10 seconds. Use enough wipes for treated surface to remain visibly wet for 10 seconds. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 10 seconds contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

[TO] [CLEAN] [DEODORIZE] [and] [SANITIZE] HARD, NONPOROUS FOOD CONTACT SURFACES:
Visible soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. [Wash or flush objects with a detergent or cleaner followed by a potable water rinse.] Wipe surface until completely wet. Treated surfaces must remain wet for 60 seconds/1-minute. [Rub [wet surface] with clean brush, sponge or cloth after 60-second contact time has expired.] [Allow to drain and/or air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 60 second contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

[FOR] SANITIZING –or– TO SANITIZE HARD NONPOROUS/NONWOOD CUTTTING BOARDS¥:
Visible soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wash or flush objects with a detergent or cleaner followed by a potable water rinse. Wipe surface until completely wet. Treated surfaces must remain wet for 60 seconds/1 minute. [Allow [equipment] surfaces to [drain] [and/or] air dry [before reuse]]. [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

[FOR] SANITIZING –or– TO SANITIZE REFRIGERATORS –and/or– FREEZERS
Visible soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Remove food [from refrigerator –and/or– freezer] and allow unit to warm to room temperature. Wipe surfaces until completely wet. Treated surfaces must remain wet for 60 seconds/1-minute. [Rub [wet surface] with clean brush, sponge or cloth after 60 second contact time has expired.] [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 1-minute contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.] [If desired, wipe with a [lint-free] cloth or paper towel.]

[FOR] SANITIZING –or– TO SANITIZE GLOVES –and/or– GLOVED HANDS
To reduce the cross contamination from area to area [in] [animal areas] [and] [the packaging and storage areas of food plants], sanitize prewashed (plastic, latex or other synthetic rubber) non-porous gloved hands with this product. Wipe [this product] on the surface of the gloves until completely wet. To sanitize, treated gloves must remain wet for [at least] 10 seconds.

DISINFECTING DIRECTIONS
[TO] [CLEAN] [DEODORIZE] [and] [DISINFECT] HARD, NONPROUS SURFACES [SUCH AS {select from Hard, Nonporous Use Surfaces}:
-or-
[TO] [CLEAN] [,] [AND] DISINFECT [AND DEODORIZE] [HARD, NONPOROUS SURFACES:] [{select from Hard, Nonporous Use Surfaces}] [IN 1 STEP] [IN ONE STEP]
Visible soil must be removed prior to disinfecting [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wipe surface until completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below –or– above –or– on this label –or– pathogen list]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [No [water] rinse required [even] on food-contact surfaces]]. [Do not rinse [with water]]. [All food contact surfaces such as appliances and kitchen countertops do not need to be rinsed [with water]]. [A water rinse is not required.]
[TO] [CLEAN] [DEODORIZE] [and] [DISINFECT] HARD, NONPROUS FOOD CONTACT SURFACES [SUCH AS {select from Hard, Nonporous Use Surfaces}:
-or-
[TO] [CLEAN] [,] [AND] DISINFECT [AND DEODORIZE] [HARD, NONPOROUS SURFACES:] [{select from Hard, Nonporous Use Surfaces}] [IN 1 STEP] [IN ONE STEP]
Visible soil must be removed prior to disinfecting [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wipe surface until completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below –or– above –or– on this label –or– pathogen list]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [No [water] rinse required [even] on food-contact surfaces]]. [Do not rinse [with water]]. [All food contact surfaces such as appliances and kitchen countertops do not need to be rinsed [with water]]. [A water rinse is not required.]

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (GST) (for spray products). Sixty carriers must be tested against each of the three batches of the product at the active ingredient(s) lower certified limit(s) (LCL). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of 1.0×10^6) and not above 7.0 (corresponding to a geometric mean density of 1.0×10^7) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <6.0 or >7.0 invalidates the test. For GST, a mean log density of at least 5.0 (corresponding to a geometric mean density of 1.0×10^5) and not above 6.5 (corresponding to a geometric mean density of 3.2×10^6) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing (GST) is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results for both UDM and GST methods. To be deemed an

effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be 1 x 10^4 CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*.:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.

2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings**:**

For an emerging viral pathogen that is a/an…	*Qualifying criterion*
Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus

Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

1.	**MRID**	50615701	**Study Completion Date:**	06/18/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24873		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.4		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 20°C	RH: 6%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing was performed at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. This testing was not performed under EPA or FDA Good Laboratory Practices. According to the results, the organism is resistant to: Cefazolin, Gentamicin, and Trimethoprim/Sulfa.		

2.	**MRID**	50615702	**Study Completion Date:**	06/05/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24874		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Bordetella pertussis* (ATCC 12743)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.1		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		

Soil load	5% FBS		
Carrier type, # per lot	Glass slides, 10 per batch		
Test conditions	**Contact time**: 53 sec.	**Temp:** 19°C	RH: 9%
Neutralizer	20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Protocol Amendments: This amendment is to clarify the exposure time. The exposure time is being amended from 53 seconds Minutes" to "53 seconds".		

3.	**MRID**	50615703	**Study Completion Date:**	06/01/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24869		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Campylobacter jejuni* (ATCC 29428)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.2		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ **1** ☒ **2** ☐ **3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 22°C	RH: 14%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)				

4.	**MRID**	50615704	**Study Completion Date:**	06/05/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24859		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Enterobacter aerogenes* (ATCC 13048)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.5		
Application Method		Towelette wipes – using 4 passes		
	Name/ID	2017-JigSAW-015		
	Lots	2017-JigSAW-015-1: 19.0% Ethanol		

Test Substance Preparation	☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 & 75 sec.	**Temp:** 20-21°C	RH: 15%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Test History:** Testing performed on 1/31/18 resulted in failing efficacy results for Lot 2017-JigSAW-015-2. Per Sponsor's request, the protocol was amended to add additional testing of Lot 2017-JigSAW-015-2 using an exposure time of 60 seconds and a soil load of 6% fetal bovine serum (See Protocol Amendment 1). Testing performed under these parameters on 2/14/18 resulted in failing efficacy results. Per Sponsor's request, the protocol was amended to add additional testing of Lot 2017-JigSAW-015-2 using an exposure time of 75 seconds and a soil load of 5% fetal bovine serum (See Protocol Amendment 2). Testing performed under these parameters on 3/6/18 resulted in valid test results. All Testing performed on 1/31/18, 2/14/18 and 3/6/18 are valid and presented in the body of the report. **Protocol Amendments:** 1. Per sponsor request, the protocol is being amended to perform additional testing of lot 2017-JigSAW-015-2 with a soil load of 6% and an exposure time of 60 seconds. 2. Per sponsor request, the protocol is being amended to perform additional testing of Lot 2017-JigSAW-015-2 with a soil load of 5% and an exposure time of 75 seconds. 3. This amendment is to correct a typographical error in Amendment 2. The effective date is being amended to change from "February 6, 2018" to "February 23, 2018". **Protocol Deviations:** During the organism confirmation procedures performed on 2/16/18, the subcultures were incubated at 36.0°C, instead of the temperature range of 25-30°C that is described in the incubation parameters section of the protocol. Because there was enough subculture growth to complete confirmation procedures, this deviation has no impact on the overall intent of the protocol.		

5.	**MRID**	50615705	**Study Completion Date:**	06/15/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25252		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Carbapenem Resistant *Escherichia coli* (CDC 81371)		

Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01020818.TOW.1		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 21°C	RH: 40%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic susceptibility test was performed by Accuratus Lab Services for the organism using a modified Hodge test to detect carbapenemase activity. The absence of a cloverleaf type indentation indicates that the organism does not produce carbapenemase, and is therefore, susceptible to carbapenem. **Test History:** Testing performed on 4/10/18 resulted in carrier population controls that did not meet the minimum acceptance criterion. Furthermore, the viability, carrier sterility, and neutralizing subculture medium sterility controls were not incubated (see Protocol Deviation). Population controls and test results from test date 4/10/18 are invalid and are reported in Attachment I. Neutralization confirmation control data from 4/10/18 is valid and is included in the body of the report. Testing was repeated on 4/20/18, which also resulted in a carrier population control failure. Data from 4/20/18 is not valid, and is presented in Attachment II. Testing was repeated on 4/30/18. Data generated on 4/30/18 is valid, and is included in the body of the report. **Protocol Deviation:** The protocol states that the viability, carrier sterility, and neutralizing subculture medium sterility controls will "be incubated and visually examined for growth". On test date 4/10/18, the controls were inadvertently not incubated with the test subculture tubes. Because the test results were invalidated due to carrier population controls that didn't meet minimum acceptance criteria, the lack of controls had no impact on the study.		

6.	**MRID**	50615706	**Study Completion Date:**	06/04/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24856		

Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.7		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 21°C	RH: 15%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Test History:** Testing performed on 2/1/18 resulted in population control results that were below the minimum acceptance criterion. Due to this, population control results and test results from testing performed on 2/1/18 are considered invalid and are presented in Attachment I. Neutralization confirmation controls as well as purity, viability, and sterility controls from testing performed on 2/1/18 are considered valid and are presented in the body of this report. Testing was repeated on 2/14/18 and resulted in valid test and control results, which are presented in the body of this report. Due to valid neutralization confirmation control results, this control was not repeated on 2/14/18. Testing was performed the same on each test date unless otherwise noted.		

7.	**MRID**	50615707	**Study Completion Date:**	06/12/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24872		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Shigella flexneri* serovar 1B (ATCC 9380)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.6		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		

Carrier type, # per lot	Glass slides, 10 per batch		
Test conditions	**Contact time**: 53 sec.	**Temp:** 18°C	RH: 6%
Neutralizer	20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)			

8.	**MRID**	50615708	**Study Completion Date:**	06/01/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25254		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01020818.TOW.2		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ **1** ☒ **2** ☐ **3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 19°C	RH: 21%
Neutralizer		20 mL Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic susceptibility test was performed by Accuratus Lab Services on the organism using the Etest assay to verify the antimicrobial resistance pattern. Following incubation, the minimum inhibitory concentration (MIC) was read where the edge of the inhibition ellipse intersected the side of the strip.		

9.	**MRID**	50615709	**Study Completion Date:**	06/01/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24857		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Vancomycin Resistance *Enterococcus faecalis* -VRE (ATCC 51575)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01122017.TOW.2		
Application Method		Towelette wipes – using 4 passes		
	Name/ID	2017-JigSAW-015		

Test Substance Preparation	**Lots** ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 53 sec.	**Temp:** 19°C	RH: 6%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic susceptibility test was performed by Accuratus Lab Services on the organism using the Kirby Bauer susceptibility assay to verify the antimicrobial resistance pattern. Following incubation and storage, the zone (diameter) of inhibition showing no visible growth was measured. IF no zone was present, the size of the disc was reported (6 mm). **Protocol Deviation:** During testing on 2/1/18, the technician inadvertently neutralized the test substance after an exposure time of 53 seconds. Per the protocol, the exposure time should be 60 seconds. No impact on the overall intent of the protocol. The Sponsor was contacted and indicated that the deviation was acceptable, as both lots of test substance demonstrated efficacy at the 53 second exposure time.		

10.	**MRID**	50615710	**Study Completion Date:**	06/01/2018
Study Objective		Hard, non-porous surface disinfectant – additional bacteria		
Study Title		Pre-Saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25253		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Vancomycin Intermediate Resistance *Staphylococcus aureus* - VISA (CDC HIP 5836)		
Test Method		According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01020818.TOW.3		
Application Method		Towelette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		6% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**: 80 sec.	**Temp:** 20°C	RH: 22%
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting,		Antibiotic susceptibility test was performed by Accuratus Lab Services on the organism using the Etest assay to verify the antimicrobial resistance pattern. Following incubation, the		

control failures, neutralizer, etc.)	minimum inhibitory concentration (MIC) was read where the edge of the inhibition ellipse intersected the side of the strip.

11.	**MRID**	50615711	**Study Completion Date:**		05/04/18		
Study Objective		Hard, non-porous surface disinfectant – virus					
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection					
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24976					
Test Method		ASTM E2053-11, Protocol #GJI01122017.AFLU (*copy provided*)					
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Avian Influenza A (H5N1) virus Strain VNH5N1-PR8/CDC-RG, CDC #2006719965					
Indicator Cell Culture		MDCK cells (canine kidney), ATCC CCL-34					
Test Medium		Dulbecco's Minimum Essential Medium (D-MEM) + 2 µg/mL TPCK-trypsin, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots ☐ **1** ☒ **2** ☐ **3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		6% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	15 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

12.	**MRID**	50615712	**Study Completion Date:**	06/04/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25305		
Test Method		ASTM E2053-11, Protocol #GJI01020818.AFLU (*copy provided*)		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Avian Influenza A (H7N9) virus Strain wildtype A/Anhui/1/2013, CDC #2013759189		
Indicator Cell Culture		MDCK cells (canine kidney), ATCC CCL-34		
Test Medium		Dulbecco's Minimum Essential Medium (D-MEM) + 2 µg/mL TPCK-trypsin, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B		
Application Method		Towlette wipes – using 4 passes		

<table>
<tr><td rowspan="2">Test Substance Preparation</td><td>Name/ID</td><td colspan="6">2017-JigSAW-015</td></tr>
<tr><td>Lots
☐ 1 ☒ 2 ☐ 3</td><td colspan="6">2017-JigSAW-015-1: 19.0% Ethanol
2017-JigSAW-015-2: 19.0% Ethanol
Tested concentration: LCL</td></tr>
<tr><td colspan="2">Preparation</td><td colspan="6">Ready-to-use</td></tr>
<tr><td colspan="2">Soil load</td><td colspan="6">6% FBS</td></tr>
<tr><td colspan="2">Carrier type, # per lot</td><td colspan="6">Glass carriers</td></tr>
<tr><td colspan="2">Test conditions</td><td>Contact time</td><td>15 sec.</td><td>Temp</td><td>21.5°C</td><td>RH</td><td>--</td></tr>
<tr><td colspan="2">Neutralizer</td><td colspan="6">Sephadex Gel Filtration Columns</td></tr>
<tr><td colspan="2">Reviewer comments
(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)</td><td colspan="6">Protocol Amendment:
Per Sponsor request, this protocol is amended to include the following modifications, which will align this protocol with the February 2018 version of the 810.2000 and 810.2200 Product Performance Test Guidelines:

A. The study acceptance criteria section is updated to reflect that a valid test requires 1) that at least 4.8 $\log_{10}$ of infectivity per carrier be recovered from the dried virus control film; 2) that a ≥3 $\log_{10}$ reduction in titer must be demonstrated; 3) if cytotoxicity is evident, at least a 3 $\log_{10}$ reduction in titer must be demonstrated beyond the cytotoxic level; 4) that the cell controls be negative for infectivity. An efficacious product does not need to demonstrate complete inactivation at all dilutions.
B. The Product Performance Test Guidelines in the references section, OCSPP 810.2000 and 810.2200, will be updated to reflect the February 2018 version of the guidelines accordingly:
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides - Guidance for Efficacy Testing, February 2018.
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing, February 2018.
C. Calculations
For Calculation of Titers section of the protocol, the calculation listed is to determine the TCID50/volume inoculated.
To calculate TClD50/carrier:
(Antilog of dried virus control TClD50*) x (volume inoculated per carrier/ volume inoculated per well) = Y
Log of Y = the TClD50/carrier (Example: $10^{5.80}$ or 5.80 $\log_{10}$)</td></tr>
</table>

	*This is the TClD50 value calculated based on the volume inoculated per well as described in the Calculation of Titers section of the protocol. The following calculation will be used to calculate the log reduction per volume inoculated per well and the log reduction per carrier: Dried Virus Control log_{10} TClD50 - Test Substance log_{10} TClD50 = Log Reduction D. To include the manufacture date of each test substance lot, which will be included in the report. Per the test substance certificates of analysis, the manufacture date for Batch #2017-JigSAW-015-1 is 12/06/2017 and for Batch #2017-JigSAW-015-2 is 12/07/2017.

13.	**MRID**	50615713	**Study Completion Date:**	05/03/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24963		
Test Method		ASTM E2053-11, Protocol #GJI01122017.HSV1 (*copy provided*)		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Herpes simplex virus type 1, ATCC VR-733, Strain F(1)		
Indicator Cell Culture		Vero cells, ATCC CCL-81		
Test Medium		Minimum Essential Medium (MEM) with 5% (v/v) heat-inactivated FBS + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B		
Application Method		Towlette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		6% FBS		
Carrier type, # per lot		Glass carriers		
Test conditions		**Contact time** 15 sec.	**Temp** 22°C	**RH** --
Neutralizer		Sephadex Gel Filtration Columns		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)				

14.	**MRID**	50615714	**Study Completion Date:**	05/04/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		

Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25307					
Test Method		ASTM E2053-11, Protocol #GJI01020818.HSV2 (*copy provided*)					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Herpes simplex virus type 2, ATCC VR-734, Strain G					
Indicator Cell Culture		Vero cells, ATCC CCL-81					
Test Medium		Minimum Essential Medium (MEM) with 5% (v/v) heat-inactivated FBS + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		6% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	15 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

15.	**MRID**	50615715	**Study Completion Date:**	06/07/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25306		
Test Method		ASTM E2053-11, Protocol #GJI01020818.FLUB (*copy provided*)		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72		
Indicator Cell Culture		MDCK cells (canine kidney), ATCC CCL-34		
Test Medium		Dulbecco's Minimum Essential Medium (D-MEM) + 2 µg/mL TPCK-trypsin, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B		
Application Method		Towlette wipes – using 4 passes		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		6% FBS		
Carrier type, # per lot		Glass carriers		
Test conditions		**Contact time**	15 sec.	**Temp** 22°C **RH** --

Neutralizer	Sephadex Gel Filtration Columns
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	

16.	**MRID**	50615716	**Study Completion Date:**		04/20/18		
Study Objective		Hard, non-porous surface disinfectant – virus					
Study Title		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test – Mumps Virus					
Testing Lab, Lab Study ID		Microbac Laboratories, Inc., Project ID #512-220					
Test Method		ASTM E2053-11, Protocol ID #512.1.03.08.18 *(copy provided*)					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Mumps Virus, Strain; Jones, ATCC VR-1438					
Indicator Cell Culture		LLC-MK2 cells, ATCC CCL-7.1					
Test Medium		Minimum Essential Medium (MEM) + 2% FBS					
Application Method		Towlette wipes – using 6 motions					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		5% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	25 sec.	**Temp**	21°C	**RH**	~12%
Neutralizer		MEM + 2% FBS					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Protocol Amendment: Protocol, Page 5, Figure 1: Figure 1 states "2 replicated" for Product Lot 1, Product Lot 2, and Plate Recovery Control. It should state "1 replicate". This amendment serves to correct the typographical error in the Protocol.					

17.	**MRID**	50615717	**Study Completion Date:**	05/02/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24139		
Test Method		ASTM E2053-11, Protocol #GJI01090117.PFLU (*copy provided*)		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Parainfluenza virus type 3, ATCC VR-93, Strain C243		

Indicator Cell Culture		MDBK cells (bovine kidney), ATCC CCL-22					
Test Medium		Minimum Essential Medium (MEM) with 1% (v/v) heat-inactivated FBS + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-008					
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-008-1: 19.1% Ethanol 2017-JigSAW-008-2: 19.1% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		6% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	15 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendment:** Per Sponsor request, this protocol is amended to include the following modifications, which will align this protocol with the February 2018 version of the 810.2000 and 810.2200 Product Performance Test Guidelines: A. The study acceptance criteria section is updated to reflect that a valid test requires 1) that at least 4.8 $\log_{10}$ of infectivity per carrier be recovered from the dried virus control film; 2) that a ≥3 $\log_{10}$ reduction in titer must be demonstrated; 3) if cytotoxicity is evident, at least a 3 $\log_{10}$ reduction in titer must be demonstrated beyond the cytotoxic level; 4) that the cell controls be negative for infectivity. An efficacious product does not need to demonstrate complete inactivation at all dilutions. B. The Product Performance Test Guidelines in the references section, OCSPP 810.2000 and 810.2200, will be updated to reflect the February 2018 version of the guidelines accordingly: - U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides - Guidance for Efficacy Testing, February 2018. - U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing, February 2018. C. Calculations For Calculation of Titers section of the protocol, the calculation listed is to determine the TCID50/volume inoculated.						

	To calculate TClD50/carrier: (Antilog of dried virus control TClD50*) x (volume inoculated per carrier/ volume inoculated per well) = Y Log of Y = the TClD50/carrier (Example: $10^{5.80}$ or 5.80 log_{10}) *This is the TClD50 value calculated based on the volume inoculated per well as described in the Calculation of Titers section of the protocol. The following calculation will be used to calculate the log reduction per volume inoculated per well and the log reduction per carrier: Dried Virus Control log_{10} TClD50 - Test Substance log_{10} TClD50 = Log Reduction D. To include the manufacture date of each test substance lot, which will be included in the report. Per the test substance certificates of analysis, the manufacture date for Batch #2017-JigSAW-008-1 is 07/13/2017 and for Batch #2017-JigSAW-008-2 is 07/13/2017.

18.	**MRID**	50615718	**Study Completion Date:**	05/21/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test – Murine Norovirus		
Testing Lab, Lab Study ID		Microbac Laboratories, Inc., Project ID #512-226		
Test Method		ASTM E2053-11, Protocol ID #512.2.04.05.18 *(copy provided*)		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Murine Norovirus (MNV), Strain: MNV-G, Yale University		
Indicator Cell Culture		RAW 264.7, ATCC TIB-71		
Test Medium		Dulbecco's Modified Eagle Medium (D-MEM) + 2% FBS		
Application Method		Towlette wipes – using 6 motions		
Test Substance Preparation	**Name/ID**	2017-JigSAW-015		
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL		
	Preparation	Ready-to-use		
Soil load		6% FBS		
Carrier type, # per lot		Glass carriers		
Test conditions		**Contact time** 120 sec.	**Temp** 21°C	**RH** ~37%
Neutralizer		MEM + 2% FBS		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)				

19.	**MRID**	50615719	**Study Completion Date:**	06/06/18

Study Objective		Hard, non-porous surface disinfectant – virus					
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection					
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25281					
Test Method		ASTM E2053-11, Protocol #GJI01020818.R37 (*copy provided*)					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Rhinovirus type 37, ATCC VR-1147, Strain 151-1					
Indicator Cell Culture		MRC-5 cells (human embryonic lung), ATCC CCL-171					
Test Medium		Minimum Essential Medium (MEM) with 10% (v/v) heat-inactivated FBS + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		5% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	53 sec.	**Temp**	21.5°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

20.	**MRID**	50615720	**Study Completion Date:**	05/04/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24969		
Test Method		ASTM E2053-11, Protocol #GJI01122217.ROT (*copy provided*)		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Rotavirus, ATCC VR-2018, Strain WA		
Indicator Cell Culture		MA-104 cells (Rhesus monkey kidney), ATCC CCL-2378.1		
Test Medium		Minimum Essential Medium (MEM) + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin, and 2.0 mM L-glutamine		
Application Method		Towlette wipes – using 4 passes		
	Name/ID	2017-JigSAW-015		

Test Substance Preparation	**Lots** ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		6% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	30 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendment:** This protocol is amended to be updated to follow the newly revised EPA Product Performance Guidelines. The following changes are to be made to this protocol: 1. Include the following formula, in the Calculation of Titers, for calculation of the TClD50 per Carrier: TClD50 per carrier surface = Log [(TClD50 per inoculum) (µL of virus per carrier surface / µL of inoculum per well)] 2. Change the Study Acceptance Criteria from "that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film" to "that the minimum recoverable virus end point titer of $>10^{4.80}$ viable viral particles per test carrier/surface be demonstrated" 3. From the Study Acceptance Criteria, remove the wording "Note: An efficacious product must demonstrate complete inactivation of the virus at all dilutions from the test carrier" 4. Change Reference #3 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides - Guidance for Efficacy Testing, February 2018" 5. Change Reference #4 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing, February 2018".					

21.	**MRID**	50615721	**Study Completion Date:**	05/03/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24975		
Test Method		ASTM E2053-11, Protocol #GJI01122017.DHBV (*copy provided*)		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Duck Hepatitis B virus as a surrogate for human Hepatitis B virus, 9/1/15 strain, Hepadnavirus Testing Inc.		
Indicator Cell Culture		Pekin breed hatchling ducks from Abendroth Hatchery by Valley Research Institute (VRI), March 1, 2018		

Test Medium		Leibovitz L-15 medium + 0.1% glucose, 10 µg/mL gentamicin, 100 units/mL penicillin, 10 µM dexamethasone, 10 µg/mL insulin, and 20 mM HEPES					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots ☐ 1 ☒ 2 ☐ 3	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		5% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	20 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendment:** This protocol is amended to be updated to follow the newly revised EPA Product Performance Guidelines. The following changes are to be made to this protocol: 1. Include the following formula, in the Calculation of Titers, for calculation of the TClD50 per Carrier: TClD50 per carrier surface = Log [(TClD50 per inoculum) (µL of virus per carrier surface / µL of inoculum per well)] 2. Change the Study Acceptance Criteria from "that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film" to "that the minimum recoverable virus end point titer of $>10^{4.80}$ viable viral particles per test carrier/surface be demonstrated" 3. From the Study Acceptance Criteria, remove the wording "Note: An efficacious product must demonstrate complete inactivation of the virus at all dilutions from the test carrier" 4. Change Reference #3 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides - Guidance for Efficacy Testing, February 2018" 5. Change Reference #4 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing, February 2018". For clarity, this protocol is amended to indicate that the identity, strength, purity, and uniformity testing was performed following 40 CFR Part 160 GLP regulations.					

22.	**MRID**	50615722	**Study Completion Date:**	05/02/18
Study Objective		Hard, non-porous surface disinfectant – virus		

Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus					
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24970					
Test Method		ASTM E2053-11, Protocol #GJI01122017.BVD (*copy provided*)					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Bovine Viral Diarrhea virus as a surrogate for Human Hepatitis C virus, NADL strain, ATCC VR-1422					
Indicator Cell Culture		Bovine turbinate (BT) cells, ATCC CRL-1390					
Test Medium		Minimum Essential Medium (MEM) with 5% (v/v) heat-inactivated horse serum + 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots **☐ 1 ☒ 2 ☐ 3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		5% horse serum					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	20 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendment:** This protocol is amended to be updated to follow the newly revised EPA Product Performance Guidelines. The following changes are to be made to this protocol: 1. Include the following formula, in the Calculation of Titers, for calculation of the TClD50 per Carrier: TClD50 per carrier surface = Log [(TClD50 per inoculum) (µL of virus per carrier surface / µL of inoculum per well)] 2. Change the Study Acceptance Criteria from "that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film" to "that the minimum recoverable virus end point titer of $>10^{4.80}$ viable viral particles per test carrier/surface be demonstrated" 3. From the Study Acceptance Criteria, remove the wording "Note: An efficacious product must demonstrate complete inactivation of the virus at all dilutions from the test carrier" 4. Change Reference #3 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides - Guidance for Efficacy Testing, February 2018" 5. Change Reference #4 to "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200:					

	Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing, February 2018".

23.	**MRID**	50615723	**Study Completion Date:**	05/03/18			
Study Objective		Hard, non-porous surface disinfectant – virus					
Study Title		Virucidal Efficacy of Pre-saturated Towelettes for Hard Surface Disinfection					
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25065					
Test Method		ASTM E2053-11, Protocol #GJI01122017.HIV (*copy provided*)					
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Human Immunodeficiency Virus type 1, Strain HTLV-III_B					
Indicator Cell Culture		MT-2 cells (human T-cell leukemia cells)					
Test Medium		RPMI-1640 with 15% (v/v) heat-inactivated FBS + 50 µg/mL gentamicin and 2.0 mM L-glutamine					
Application Method		Towlette wipes – using 4 passes					
Test Substance Preparation	**Name/ID**	2017-JigSAW-015					
	Lots ☐ **1** ☒ **2** ☐ **3**	2017-JigSAW-015-1: 19.0% Ethanol 2017-JigSAW-015-2: 19.0% Ethanol Tested concentration: LCL					
	Preparation	Ready-to-use					
Soil load		5% FBS					
Carrier type, # per lot		Glass carriers					
Test conditions		**Contact time**	15 sec.	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

V. RESULTS

Bactericidal Activity					
MRID No.	**Contact Time**	**Organism**	**No. Carriers Exhibiting Growth/ Total Carriers**		**Average Carrier Population Control Log (CFU/Carrier)**
			2017-JigSAW-015-1	**2017-JigSAW-015-2**	
50615701	53 sec.	Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)	0/10	0/10	4.42
50615702		*Bordetella pertussis* (ATCC 12743)	0/10	0/10	6.04
50615703		*Campylobacter jejuni* (ATCC 29428)	0/10	0/10	5.81

50615704	(1/31/18) 53 sec.	*Enterobacter aerogenes* (ATCC 13048)	0/10	1/10	5.46
	(2/14/18) 60 sec.		--	1/10	5.60
	(3/6/18) 75 sec.		--	0/10	5.52
50615705	53 sec.	Carbapenem Resistant *Escherichia coli* (CDC 81371)	0/10	0/10	5.03
50615706		*Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)	0/10	0/10	5.34
50615707		*Shigella flexneri* serotype 1B (ATCC 9380)	0/10	0/10	5.92
50615708		Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677)	0/10	0/10	4.56
50615709		Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575)	0/10	0/10	4.78
50615710	80 sec.	Vancomycin Intermediate Resistant *Staphylococcus aureus* – VISA (CDC HIP 5836)	0/10	0/10	5.05

Virucidal Activity						
MRID No.	**Contact Time**	**Organism**	**Results**			**Plate Recovery Control**
				2017-JigSAW-015-1	**2017-JigSAW-015-2**	
			Description	**Rep. 1**	**Rep. 1**	**$TCID_{50}$/100 µL ($TCID_{50}$/carrier)**
50615711	15 sec.	Avian Influenza A (H5N1) Virus, Strain VNH5N1-PR8/CDC-RG, CDC #2006719965	Complete Inactivation	10^{-1} to 10^{-8} dilutions	10^{-1} to 10^{-8} dilutions	$10^{5.50}$
			$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
			Log_{10} Reduction	≥5.00	≥5.00	
50615712		Avian Influenza A (H7N9) virus, Strain wildtype A/Anhui/1/2013, CDC #2013759189	Complete Inactivation	10^{-3} to 10^{-7} dilutions	10^{-1} to 10^{-7} dilutions	$10^{5.50}$ ($10^{5.80}$)
			$TCID_{50}$/100 µL	$*10^{2.50}$	$\leq 10^{0.50}$	
			$TCID_{50}$/carrier	$10^{2.80}$	$\leq 10^{0.80}$	
			Log_{10} Reduction	≥3.00	≥5.00	
50615713		Herpes simplex virus type 1, ATCC VR-733, Strain F(1)	Complete Inactivation	10^{-1} to 10^{-7} dilutions	10^{-1} to 10^{-7} dilutions	$10^{6.75}$
			$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
			Log_{10} Reduction	≥6.25	≥6.25	

50615714		Herpes simplex virus type 2, ATCC VR-734, Strain G	Complete Inactivation	10^{-1} to 10^{-8} dilutions	10^{-1} to 10^{-8} dilutions	$10^{4.50}$
			$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	
50615715		Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72	Complete Inactivation	10^{-1} to 10^{-7} dilutions	10^{-1} to 10^{-7} dilutions	$10^{4.50}$
			$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	
50615719	53 sec.	Rhinovirus type 37, ATCC VR-1147, Strain 151-1	Complete Inactivation	10^{-1} to 10^{-6} dilutions	10^{-1} to 10^{-6} dilutions	$10^{4.50}$
			$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	
50615720	30 sec.	Rotavirus, ATCC VR-2018, Strain WA	Complete Inactivation	10^{-2} to 10^{-8} dilutions	10^{-1} to 10^{-8} dilutions	$10^{6.00}$ ($10^{6.30}$)
			$TCID_{50}$/100 µL	$*10^{0.75}$	$\leq 10^{0.50}$	
			$TCID_{50}$/carrier	$10^{1.05}$	$\leq 10^{0.80}$	
			Log_{10} Reduction	5.25	≥5.50	
			Description	**Rep. 1**	**Rep. 1**	**$TCID_{50}$/200µL**
50615723	15 sec.	Human Immuno-deficiency Virus type 1, Strain $HTLV\text{-}III_B$	Complete Inactivation	10^{-2} to 10^{-7} dilutions	10^{-2} to 10^{-7} dilutions	$10^{5.50}$
			$TCID_{50}$/200 µL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	
			Description	**Rep. 1**	**Rep. 1**	**Log_{10} $TCID_{50}$/mL (Log_{10} $TCID_{50}$/carrier)**
50615716	25 sec.	Mumps Virus, Strain Jones, ATCC VR-1438	Complete Inactivation	10^{-1} to 10^{-7} dilutions	10^{-1} to 10^{-7} dilutions	5.75 (5.05)
			$TCID_{50}$/mL	≤1.50	≤1.50	
			$TCID_{50}$/carrier	≤0.80	≤0.80	
			Log_{10} Reduction	≥4.25	≥4.25	
50615718	120 sec.	Murine Norovirus (MNV), Strain: MNV-G, Yale University	Complete Inactivation	10^{-1} to 10^{-7} dilutions	10^{-1} to 10^{-7} dilutions	5.75 (5.05)
			$TCID_{50}$/mL	≤2.50	≤2.50	
			$TCID_{50}$/carrier	≤1.80	≤1.80	
			Log_{10} Reduction	≥3.25	≥3.25	

Virucidal Activity						
MRID No.	**Contact Time**	**Organism**	**Results**			**Plate Recovery Control** $TCID_{50}$/100 µL ($TCID_{50}$/carrier)
				Batch# 2017-JigSAW-008-1	**Batch# 2017-JigSAW-008-2**	
50615717	15 sec.	Parainfluenza virus type 3, ATCC VR-93, Strain C243	**Description**	**Rep. 1**	**Rep. 1**	$10^{6.50}$ ($10^{6.80}$)
			Complete Inactivation	10^{-2} to 10^{-7} dilutions	10^{-3} to 10^{-7} dilutions	
			*$TCID_{50}$/100 µL	$10^{0.75}$	$10^{2.00}$	
			$TCID_{50}$/carrier	$10^{1.05}$	$10^{2.30}$	
			Log_{10} Reduction	5.75	4.50	

Virucidal Activity							
MRID No.	**Contact Time**	**Organism**	**Results**				
				Batch# 2017-JigSAW-015-1		**Batch# 2017-JigSAW-015-2**	
50615721	20 sec.	Duck Hepatitis B, Strain 9/1/15 (surrogate for human HBV)	**Description**	**Rep. 1**	**Rep. 2**	**Rep. 1**	**Rep. 2**
			Complete Inactivation	10^{-2} to 10^{-4} dilutions	10^{-1} to 10^{-4} dilutions	10^{-1} to 10^{-4} dilutions	10^{-2} to 10^{-4} dilutions
			*$TCID_{50}$/250µL	$10^{1.50}$	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{1.00}$
			Log_{10} $TCID_{50}$/carrier	$10^{1.40}$	$\leq 10^{0.40}$	$\leq 10^{0.40}$	$10^{0.90}$
			Log_{10} MPN	1.37983	≤0.00000	≤0.00000	0.78254
			MPN Log Reduction	≥4.77	≥4.77	≥4.77	≥4.77
			Plate Recovery Control $TCID_{50}$/250 µL ($TCID_{50}$/carrier) (Log_{10} MPN)	Rep. 1		Rep. 2	
				$10^{5.25}$ ($10^{5.15}$) (5.05894)		$10^{5.75}$ ($10^{5.65}$) (5.55827)	
50615722		Bovine Viral Diarrhea virus, Strain NADL, ATCC VR-1422 (surrogate for human HCV)	Complete Inactivation	10^{-2} to 10^{-4} dilutions	10^{-3} to 10^{-4} dilutions	10^{-2} to 10^{-4} dilutions	10^{-3} to 10^{-4} dilutions
			*$TCID_{50}$/100µL	$\leq 10^{0.50}$	$10^{0.75}$	$\leq 10^{0.50}$	$10^{1.25}$
			Log_{10} $TCID_{50}$/carrier	$\leq 10^{0.80}$	$10^{1.05}$	$\leq 10^{0.80}$	$10^{1.55}$
			Log_{10} MPN	≤0.00000	0.41128	<0.00000	1.05884
			MPN Log Reduction	≥4.49	≥4.49	≥4.49	≥4.49
			Plate Recovery Control $TCID_{50}$/100 µL ($TCID_{50}$/carrier) (Log_{10} MPN)	Rep. 1		Rep. 2	
				$10^{4.50}$ ($10^{4.80}$) (4.37983)		$10^{5.75}$ ($10^{6.05}$) (5.32999)	

*****Both Cytotoxicity and Neutralization control results showed the absence of cytotoxicity, leading to the lab's conclusion that test substance cytotoxicity was not observed in either batch at any dilution tested for the indicated studies.

VI. CONCLUSION

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50615701	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	MDR *Acinetobacter baumannii* (ATCC 19606)	**Yes**
50615702	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	*Bordetella pertussis* (ATCC 12743)	**Yes**
50615703	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	*Campylobacter jejuni* (ATCC 29428)	**Yes**
50615704	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	75 sec.	5%	None	*Enterobacter aerogenes* (ATCC 13048)	**Yes**
50615705	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	Carbapenem Resistant	**Yes**

							Escherichia coli (CDC 81371)	
50615706	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	*Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)	**Yes**
50615707	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	*Shigella flexneri* serotype 1B (ATCC 9380)	**Yes**
50615708	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677)	**Yes**
50615709	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)	**Yes**
50615710	Bactericidal activity	Hard, non-porous surfaces	RTU Towelettes	80 sec.	6%	None	Vancomycin Intermediate Resistant *Staphylococcus aureus* – VISA (CDC HIP 5836)	**Yes**
50615711	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Avian Influenza A (H5N1) (CDC #2006719965)	**Yes**
50615712	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Avian Influenza A (H7N9) (CDC #2013759189)	**Yes**
50615713	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Herpes simplex virus type 1 (ATCC VR-733)	**Yes**
50615714	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Herpes simplex virus type 2 (ATCC VR-734)	**Yes**
50615715	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Influenza B virus (ATCC VR-823)	**Yes**
50615716	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	25 sec.	5%	None	Mumps Virus, Strain Jones (ATCC VR-1438)	**Yes**
50615717	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	6%	None	Parainfluenza virus type 3 (ATCC VR-93)	**Yes**
50615718	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	120 sec.	6%	None	Murine Norovirus (MNV), Strain MNV-G, Yale University	**Yes**
50615719	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	53 sec.	5%	None	Rhinovirus type 37 (ATCC VR-1147)	**Yes**

50615720	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	30 sec.	6%	None	Rotavirus (ATCC VR-2018)	**Yes**
50615721	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	20 sec.	5%	None	Duck Hepatitis B virus, Strain 9/1/15 (surrogate for HBV)	**Yes**
50615722	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	20 sec.	5%	None	Bovine Viral Diarrhea virus, Strain NADL (ATCC VR-1422) (surrogate for HCV)	**Yes**
50615723	Virucidal activity	Hard, non-porous surfaces	RTU Towelettes	15 sec.	5%	None	Human Immunodeficiency Virus type 1 (Strain HTLV-III_B)	**Yes**

Emerging Viral Pathogen Claim								
MRID (year)	**Emerging virus claim**	**Organism(s)**	**Type of Virus (viral family)**	**Surface Type**	**Application Method(s) and/or Dilution**	**Contact Time**	**Soil load**	**Study support listed virus(es)**
50442624 (2017)	Enveloped Virus, large non-enveloped virus, & small non-enveloped virus	Feline calicivirus, Strain: F9, ATCC VR-782	Small, non-enveloped virus (Caliciviridae)	Hard non-porous surface	Towelette	5 min.	5% FBS	Yes
50615719 (2018)	Enveloped Virus, large non-enveloped Virus, & small non-enveloped virus	Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)	Small, non-enveloped virus (Picornaviridae)	Hard non-porous surface	Towelette	53 sec.	5% FBS	Yes

VII. LABEL RECOMMENDATIONS (for label ver. June 2018)

1. The proposed label claims are acceptable regarding the use of the product, JigSAW, EPA Reg. No. 84150-1, as a disinfectant towelette with bactericidal activity against the following organisms for use on hard, non-porous surfaces at the indicated contact time or at 2 minutes.

Organism	Contact Time
MDR *Acinetobacter baumannii* (ATCC 19606)	60 sec.
Bordetella pertussis (ATCC 12743)	60 sec.
Campylobacter jejuni (ATCC 29428)	60 sec.
Enterobacter aerogenes (ATCC 13048)	75 sec.
Carbapenem Resistant *Escherichia coli* (CDC 81371)	60 sec.
Salmonella enterica subspecies *enterica* serovar Typhi (ATCC 6539)	60 sec.
Shigella flexneri serotype 1B (ATCC 9380)	60 sec.
Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677)	60 sec.
Vancomycin Resistant Enterococcus faecalis - VRE (ATCC 51575)	60 sec.
Vancomycin Intermediate Resistant *Staphylococcus aureus* – VISA	80 sec.

These claims **are supported** by the applicant's data.

2. The proposed label claims are acceptable regarding the use of the product, JigSAW, EPA Reg. No. 84150-1, as a disinfectant towelette with virucidal activity against the following organisms for use on hard, non-porous surfaces at the indicated contact time or at 2 minutes.

Organism	Contact Time
Avian Influenza A (H5N1) (CDC #2006719965)	15 sec.
Avian Influenza A (H7N9) (CDC #2013759189)	15 sec.
Herpes simplex virus type 1 (ATCC VR-733)	15 sec.
Herpes simplex virus type 2 (ATCC VR-734)	15 sec.
Influenza B virus (ATCC VR-823)	15 sec.
Mumps Virus, Strain Jones (ATCC VR-1438)	25 sec.
Parainfluenza virus type 3 (ATCC VR-93)	15 sec.
Murine Norovirus (MNV), Strain MNV-G, Yale University	120 sec.
Rhinovirus type 37 (ATCC VR-1147)	53 sec.
Rotavirus (ATCC VR-2018)	30 sec.
Duck Hepatitis B virus, Strain 9/1/15 (surrogate for HBV)	20 sec.
Bovine Viral Diarrhea virus (ATCC VR-1422) (surrogate for HCV)	20 sec.
Human Immunodeficiency Virus type 1 (Strain HTLV-III_B)	15 sec.

These claims **are supported** by the applicant's data.

3. The proposed label claims that the product, JigSAW (EPA Reg. File No. 84150-1), qualifies for the following emerging viral pathogens claims are acceptable.

For an emerging viral pathogen that is a/an…	*With the following supporting viruses,*	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782) & Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)	Feline calicivirus, Strain F-9, ATCC VR-782
Large, non-enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782) & Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)	Feline calicivirus, Strain F-9, ATCC VR-782
Small, non-enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782) & Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)	Feline calicivirus, Strain F-9, ATCC VR-782

These claims are **acceptable** as they are supported by the cited data, however the proposed label language should exactly match the following:
"This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:
- Enveloped Viruses
- Large, non-enveloped virus
- Small, non-enveloped virus

For an emerging viral pathogen that is a/an…	*…following the directions for use for the following organisms on the label:*

Enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782
Large, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782
Small, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782

Acceptable claim language:

[Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard,* ***[porous and/or non-porous surfaces]****. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[pathogen-specific website address]*** *for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus]. [Product name]*** *kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"

4. Throughout the label, qualify "germ", "germicidal", and "germicide" claims (e.g., in "This product is a highly effective, economical and convenient [germicide] [sanitizer] [disinfectant] for [this] use in restaurants [and taverns] [and bars] [and cafes]" and "One step germicidal wipes") according to the agency letter concerning germ claims. https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels

5. Throughout the label, remove claims to eliminate bacteria and viruses as efficacy data do not demonstrate complete kill. For example, remove "eliminates" from:

    a. "[Effective against] [Kills] [Eliminates] [Viruses† that cause] Cold [and/or] Flu [Viruses] [‡] [in 15 seconds]"
    b. "A[n] [convenient], [simple] way to [kill] [eliminate] [destroy] [remove] bacteria [and] viruses†]"
    c. "[Kills] [eliminates] [destroys] [removes] [bacteria] [and/or] [viruses†] without leaving a residue"
    d. "Kills] [eliminates] [destroys] [removes] [bacteria [and/or] viruses†] on commonly touched hard, non-porous surfaces that can be transfer points [such as doorknobs, telephones, keyboards, and light switches]"
    e. "Kills] [eliminates] [destroys] [removes] [bacteria [and/or] viruses†] on commonly touched hard, non-porous surfaces that can be transfer points [such as doorknobs, telephones, keyboards, and light switches]"

    The claim to eliminate 99.9% of bacteria is acceptable. However, please remove brackets from 99.9% when used with the word "eliminate".

6. On page 6, under Disinfecting Directions, please indicate the contact time for Feline Calicivirus of 5 minutes for every disinfection use when the contact time of "[2 minutes]" is used. Directions for use for Feline Calicivirus are considered disinfection directions, and the 2-minute contact time indicated is not sufficient for this organism.

7. On page 8, under TO DISINFECT AGAINST THE [COLD] [and/or] [FLU] VIRUS, please CHANGE "Wipe the surface is completely wet" to "Wipe until the surface is completely wet".

8. On page 10, remove references to entire genera of bacteria; Listeria, Pseudomonas, Salmonella, Staph and Strep as these imply efficacy against the entire genus rather than the specific organism tested.

9. On page 11, remove "E. coli" and "Staph" (see above comment).

10. On page 15,
    a. remove the claim "Powerful enough to kill germs…". This claim implies heightened efficacy and should be removed.

    b. remove brackets from the claim "(This product) (is) a (convenient) way to [disinfect] (sanitize (clean) (hard non-porous surfaces) your (household) (kitchen) (bathroom) (bedroom) (floor) surfaces". "Hard, non-porous surfaces" is not optional in this context.

11. On page 16,
    a. qualify the following claim by adding "hard non-porous surfaces" (without the use of brackets) after "disinfect": "The [convenient], [simple] way to clean -and/or- disinfect [all over] [your] [the] [bathroom] [kitchen] [house] [office] [work -or- office [place] [environment]] [place]".

    b. revise the claim "The [convenient], [simple] way to [disinfect] [sanitize] [clean] all over the house" to "The [convenient], [simple] way to [disinfect] [sanitize] [clean] <u>hard, non-porous surfaces</u> all over the house."

12. On page 17,
    a. remove brackets from "non-food contact" in the claim "Sanitizes [**] [non-food contact] surfaces in [just] [only] 10 seconds."

    b. qualify the following claims by adding "when use-directions for disinfection/sanitization are followed":
        - [Patent Pending] [1 Step] [One Step] [Cleaner] [,] [and] Disinfectant [,] [and] [Sanitizer] [,] [and] [Degreaser] [,] [and] [Deodorizer]
        - [Patent Pending] [1 Step] [One Step] [Cleaner] [and] Disinfectant [No pre-cleaning required]
        - [Patent Pending] [1 Step] [One Step] [Cleaner] [and] Sanitizer [No pre-cleaning required]

13. On pages 18 and 19, qualify the various virus, virucide, and virucidal claims.

14. On page 18,
    a. the following claims should be revised by adding the term "treated" in front of "Hard, Nonporous Surfaces":
    - [To] Reduce the Cross Contamination of the Flu Virus [‡] -or- [To] Kill [the] Flu Virus[es] [‡] on Hard, Nonporous Surfaces:
    - [To] Reduce the Cross Contamination of Cold and Flu Viruses [‡] -or- [To] Kill [the] Cold and Flu Virus[es] [‡] on Hard, Nonporous Surfaces
    - [To] Reduce the Cross Contamination of Cold Viruses [‡] -or- [To] Kill [the] Cold Virus[es] [‡] on Hard, Nonporous Surfaces:

    b. Replace the term "disinfects" with "sanitizes" (without the use of brackets) from the claim "[Kills] [disinfects] [eliminates] [99.9% of] Escherichia coli (E. coli) [in 60 sec(onds)] [in 1 min(ute)]". This is a sanitization claim.

c. Remove “eliminates” claims or revise to “[eliminates 99.9% of]…”. Eliminates can only be used when properly qualified.

d. Remove claims for “E. coli”, “Salmonella”, “Strep”, “Staph” and “Listeria”. See comment 5.

e. Remove “99.9(9)(9)% of” from the following claims. A 3-log reduction (99.9%) for disinfection against these organisms are acceptable:

- [Kills] [disinfects] [eliminates] [99.9(9)(9)% of] Salmonella enterica (Salmonella) [in 60 sec(onds)] [in 1 min(ute)]
- [Kills] [disinfects] [eliminates] [99.9(9)(9)% of] Streptococcus pyogenes (Strep) [in 60 sec(onds)] [in 1 min(ute)]
- [Kills] [disinfects] [eliminates] [99.9(9)(9)% of] Methicillin-Resistant Staphylococcus aureus (MRSA)) [in 90 sec(onds)] [in 1.5 min(utes)]
- [Kills] [disinfects] [eliminates] [99.9(9)(9)% of] Listeria monocytogenes (Listeria) [in 60 sec(onds)] [in 1 min(ute)]

f. On page 19, remove the claim “Effective against Listeria” or specify “…*Listeria monocytogenes*” in the claim.

g. Specify Murine Norovirus in the claims “Kills Norovirus [in] [two] [2] [minutes]” and “Effective against Norovirus [in] [two] [2] [minutes]One step germicidal wipes”. Murine norovirus is not the agency accepted surrogate for human norovirus.